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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,872	04/05/2001	Alan Solomon	044137-5029-US	3133

9629 7590 03/25/2008

MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1656	

MAIL DATE	DELIVERY MODE
03/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/825,872	SOLOMON ET AL.	
	Examiner	Art Unit	
	CHIH-MIN KAM	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,32-34,39-45,50-52,57-61,63-65 and 67-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,32-34,39-45,50-52,57,58,63,64,69 and 70* is/are allowed.

6)☒ Claim(s) *59-61,65,67 and 68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1, 32-34, 39-45, 50-52, 57-61, 63-65 and 67-70 are pending.

Applicants' amendment filed January 4, 2008 is acknowledged. Applicants' response has been fully considered. Claims 59 and 67 have been amended, and claim 66 have been cancelled. Therefore, claims 1, 32-34, 39-45, 50-52, 57-61, 63-65 and 67-70 are examined.

Withdrawn Claim Rejections - 35 USC § 102

2. The previous rejection of claims 59-61 and 65 under 35 U.S.C. 102(a) as being anticipated by Wall *et al.* (Methods in Enzymology 309, 204-219 (1999)), is withdrawn in view of applicants' amendment to the claim, and applicants' response at page 6 in the amendment filed January 4, 2008.

New Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 59-61, 65 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wall *et al.* (Methods in Enzymology 309, 204-219 (1999)) in view of Solomon *et al.* (WO 99/60024, Reference GR in IDS filed 10/25/02) and Muller-Lierheim (U.S. Patent 4,828,563).

Wall *et al.* teach agitation-stimulated fibrillogenesis of immunoglobulin light chain peptides, recombinant V_L fragments and whole Bence Jones proteins to produce a 1 mg/ml of fibril solution in phosphate-buffered saline (pages 206-208, 212-214). Since the reference

teaches the fibril solutions of immunoglobulin light chain peptides having 1 mg/ml (i.e., an effective amount), which is the concentration used for immunization as evidenced by Soloman *et al.* (US 2002/0019335; paragraphs [0159], [0160]). However, Wall *et al.* do not disclose the composition comprising an adjuvant.

Solomon *et al.* disclose synthetic fibrils comprising immunoglobulin light chains were prepared by the method of Wall *et al.*, and the fibrils were concentrated and then used to immunize Balb/c mice over a period of several weeks, and monoclonal cell lines secreting anti-fibril antibodies were produced using standard hydridoma techniques (Example 7, pages 20-21).

Muller-Lierheim discloses in the standard hydridoma technique for producing antibodies, the proteins are prepared in Freund's complete adjuvant for immunizing Balb/c mice (column 2, lines 28-41).

At the time of invention was made, it would have been obvious that one of ordinary skill in the art has been motivated to combine the three references to prepare a pharmaceutical composition comprising synthetic fibrils comprising immunoglobulin light chain peptides and a carrier as taught by Wall *et al.* and further to include an adjuvant such as Freund's complete adjuvant in the composition as taught by Solomon *et al.* and Muller-Lierheim (claims 59-61, 65 and 67) because the inclusion of an adjuvant such as Freund's complete adjuvant would improve the immune response of the antigen (i.e., synthetic fibrils) and Freund's complete adjuvant is commonly used in the standard hydridoma technique. Thus, the combined references result in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

4. Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wall *et al.* (Methods in Enzymology 309, 204-219 (1999)) in view of Solomon *et al.* (WO 99/60024, Reference GR in IDS filed 10/25/02) and Muller-Lierheim (U.S. Patent 4,828,563) as applied to claims 59-61, 65 and 67, further in view of Nishimura et al. (U.S. Patent 5,583,005).

Wall *et al.* teach agitation-stimulated fibrillogenesis of immunoglobulin light chain peptides, recombinant V_L fragments and whole Bence Jones proteins to produce a 1 mg/ml of fibril solution in phosphate-buffered saline (pages 206-208, 212-214). Since the reference teaches the fibril solutions of immunoglobulin light chain peptides having 1 mg/ml (i.e., an effective amount), which is the concentration used for immunization as evidenced by Soloman *et al.* (US 2002/0019335; paragraphs [0159], [0160]). Solomon *et al.* disclose synthetic fibrils comprising immunoglobulin light chains were prepared by the method of Wall *et al.*, and the fibrils were concentrated and then used to immunize Balb/c mice over a period of several weeks, and monoclonal cell lines secreting anti-fibril antibodies were produced using standard hydridoma techniques (Example 7, pages 20-21). Muller-Lierheim discloses in the standard hydridoma technique for producing antibodies, the proteins are prepared in Freund's complete adjuvant for immunizing Balb/c mice (column 2, lines 28-41). However, the combination of Wall *et al.*, Solomon *et al.* and Muller-Lierheim do not disclose the composition comprising an adjuvant of BCG, Corynebacterium parvum or ALUM.

Nashimura *et al.* teach human IgE can be prepared in Freund's complete adjuvant or in alum precipitation suspension (column 4, lines 47-53).

At the time of invention was made, it would have been obvious that one of ordinary skill in the art has been motivated to combine the references to prepare a pharmaceutical composition

comprising synthetic fibrils comprising immunoglobulin light chain peptides and a carrier as taught by Wall *et al.* and further to include an adjuvant such as Freund's complete adjuvant in the composition as taught by Solomon *et al.* and Muller-Lierheim or to include an adjuvant of alum as taught by Nashimura *et al.* because the inclusion of a different adjuvant such as alum would provide an alternative adjuvant for administering synthetic fibrils. Thus, the combined references result in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

Conclusion

5. Claims 59-61, 65 and 67-68 are rejected. It appears that claims 1, 32-34, 39-45, 50-52, 57-58, 63-64 and 69-70 are free of art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/
Primary Examiner, Art Unit 1656

CMK
March 20, 2008